

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The U.S. Department of Agriculture.

Verification. The demonstration of obtaining established performance (*e.g.*, accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61074, Oct. 5, 2012]

§ 331.2 Purpose and scope.

This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to plant health or plant products.

§ 331.3 PPQ select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to plant health or to plant products.

(b) PPQ select agents and toxins:

Peronosclerospora philippinensis
(*Peronosclerospora sacchari*);
Phoma glycinicola (formerly *Pyrenochaeta glycines*);
Ralstonia solanacearum;
Rathayibacter toxicus;
Sclerophthora rayssiae;
Synchytrium endobioticum;
Xanthomonas oryzae.

(c) Genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant and/or synthetic nucleic acids that encode for the functional forms of any toxin listed in

paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*; or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable select agents or non-functional toxins.

(3) Any subspecies of *Ralstonia solanacearum* except race 3, biovar 2 and all subspecies of *Sclerophthora rayssiae* except var. *zeae*, provided that the individual or entity can verify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to plant health or plant products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(f) Any select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between